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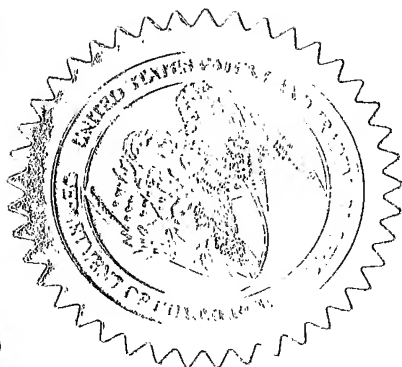
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**FILING DATE: January 26, 2004**

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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
A CATHETER ASSEMBLY WITH AN ADJUSTABLE LOOP					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		7		<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		2		<input checked="" type="checkbox"/> Other	
<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 (2 pages)		(specify): Return postcard			
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees.					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 03-1952				160.00	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:					

Respectfully submitted,

[Page 1 of 1]

Date January 26, 2004

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Signature:

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## Application Data Sheet

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Secrecy Order in Parent Appl.?::	No

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## A CATHETER ASSEMBLY WITH AN ADJUSTABLE LOOP

### FIELD OF THE INVENTION

[0001] This invention relates to a catheter system. More particularly, the invention relates to a catheter assembly with an adjustable loop.

### BACKGROUND OF THE INVENTION

[0002] Catheter systems are becoming an increasingly common way of diagnosing and treating abnormal heart conditions, in particular, heart arrhythmias. Such arrhythmias can be treated with drugs or by use of electronic devices such as pacemakers. However, neither of these treatments cures the problem but only alleviates it.

[0003] In contrast, the use of ablative techniques has been shown to cure arrhythmias. Thus, catheters having mapping electrodes and/or ablative electrodes are inserted through the vascular system of a patient's body so that a distal end of the catheter can be placed accurately in the relevant chamber of the heart. For the treatment of atrial fibrillation, the distal end is placed at or around the ostium of one or more of the pulmonary veins, in turn, to effect ablation.

[0004] In still another application for ablative catheters, the catheter may need to be placed against a wall of a blood vessel or organ, for example, in heating tumours for treatment of such tumours. It is therefore desirable that a distal end of the catheter be substantially planar so that the distal end of the catheter assembly can be placed in contact with a wall of the vessel or organ.

### BRIEF SUMMARY OF THE INVENTION

[0005] According to a first aspect of the invention, there is provided a catheter assembly that includes:

- at least one introducer, the at least one introducer defining a passage;
- an elongated tubular member slidably received within the passage of the at least one introducer, the tubular member having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; and
- and elongate shape-imparting element received in the lumen of the tubular member for

imparting a loop formation to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer, a distal end of the shape-imparting member protruding beyond the distal end of the tubular member and being anchored proximally a distal end of the introducer.

[0006] Preferably, the assembly includes at least two introducers, each introducer having a tubular member associated with it.

[0007] The first introducer may be co-axially received within the passage of the second introducer. The second tubular member associated with the second introducer may be slidable received within the passage of the second introducer.

[0008] Once again, the second tubular member may have a shape-imparting element received within its lumen. As a result, a distal part of the second tubular member may be formed in a second loop formation when the second tubular member is extended from the second introducer.

[0009] The shape-imparting element associated with the second tubular member may extend beyond a distal end of the second tubular member. The distal end of the second shape-imparting element may be anchored distally with respect to the distal end of the second tubular member but proximally with respect to the distal end of the first introducer. The anchoring of the first shape-imparting element may be in register with the anchoring of the second shape-imparting element. Both shape-imparting elements may be anchored to the first introducer.

[0010] The first introducer and the second introducer may be in the form of sleeves into which the first tubular member and the second tubular member, respectively, are withdrawn to be introduced into a patient's body. When the catheter assembly is at the desired location in the patient's body, the first tubular member and the second tubular member may be extended relative to their respective introducers to form the first loop formation and the second loop formation, respectively.

[0011] Proximal ends of the shape-imparting elements may be connected to a control mechanism so that, by applying torsion of the shape-imparting elements, a diameter of each loop formation may be adjusted.

[0012] Thus, each tubular member may form a cranked arm where it extends from its introducer, the cranked arm being arranged transversely with respect to a longitudinal axis of the introducer. The cranked arm may feed into a spiral shape forming the loop formation. Each spiral may circumscribe at least 360° and, preferably, about 540° so that, when a loop formation of maximum diameter is formed, there are electrodes arranged substantially all the way around the loop formation.

[0013] Each cranked arm may extend from the end of its associated introducer at an included angle exceeding 90° to facilitate the formation of a substantially planar loop formation at the distal end of the relevant introducer.

[0014] Advantageously, each tubular member may be manufactured in accordance with the Applicant's manufacturing technique as disclosed in its PCT Publication No. WO 02/32497 "entitled An electrical lead", the contents of which are incorporated herein by reference. The benefit of this manufacturing technique is that an unimpeded lumen is provided with conductors for the electrodes being at least partially embedded in a wall of the tubular member. Hence, a catheter assembly of small diametrical dimensions can be formed facilitating steering of the catheter assembly through the vascular system of a patient's body.

[0015] Each shape-imparting element may be in the form of a shape memory alloy wire such as a Nitinol wire which is in its superelastic state.

[0016] The proximal end of each wire may terminate in an actuating mechanism. Conveniently, each actuating mechanism may be connected to an appropriate control member of a control handle of the catheter assembly to facilitate imparting torsion to each wire. It will be appreciated that, when torsion is imparted to the wire, the cranked arm rotates about the longitudinal axis of the catheter assembly increasing or decreasing the size of the loop formation bearing in mind that the distal end of the wire is anchored.

[0017] According to a second aspect of the invention, there is provided a catheter assembly which includes:

- at least one introducer, the at least one introducer defining a passage;
- an elongate tubular member slidably received within the passage of the at least one introducer, the tubular member having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; and



an elongate shape-imparting element received in the lumen of the tubular member, a distal end of the shape-imparting element projecting beyond a distal end of the tubular member and being anchored proximally a distal end of the introducer, the arrangement being such that, when a distal portion of the tubular member is extended beyond the distal end of the introducer, the shape-imparting element imparts to the distal portion of the introducer, a cranked arm portion extending transversely relative to a longitudinal axis of the introducer and a loop formation supported on the arm so that torsion imparted to a proximal end of the shape-imparting element causes rotation of the arm of the shape imparting element about the longitudinal axis of the introducer to cause an adjustment in a diameter of the loop formation of the distal portion of the tubular member.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0018] An embodiment of the invention is now described by way of example with reference to accompanying drawings in which:

[0019] FIG. 1 shows a schematic side view of a catheter assembly, in accordance with an embodiment of the invention;

[0020] FIG. 2 shows a schematic end view of the catheter assembly; and

[0021] Figure 3 shows a schematic, three dimensional view of the configuration of the catheter assembly.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

[0022] In the drawings, reference numeral 10 generally designates a catheter assembly, in accordance with an embodiment of the invention.

[0023] The catheter assembly 10 includes a first introducer in the form of a sleeve 12 coaxially received within a passage 16 of a second introducer, also in the form of a sleeve 14. The first sleeve 12 defines a passage 18.

[0024] A first elongate tubular member 20 is slidably received within the passage 18 of the sleeve 12. Similarly, a second tubular member 22 is slidably received within the passage 16 of sleeve 14. Each tubular member 20, 22 is manufactured in accordance with the Applicant's manufacturing technique as disclosed in its PCT publication number WO 02/32497

entitled "An electrical lead". As indicated earlier in this specification, the contents of that earlier patent application are incorporated herein by reference.

[0025] While not shown in the drawings, a plurality of electrodes are arranged at spaced intervals along the tubular members 20, 22. The electrodes on the tubular members 20 and 22 can be used by sensing and/or ablation or heating purposes.

[0026] As illustrated, a distal portion 24 of the tubular member 20 is formed into a loop formation 26. Similarly, a distal portion 28 of the tubular member 22 is formed into a loop formation 30.

[0027] As described in Applicant's International Patent Publication No. WO 03/094764 dated 9 May 2003 and entitled "An ablation catheter", the contents of which are also incorporated herein by reference, electrodes in the distal loop formation 26 can, typically, be used by sensing of electrical activity in walls of a patient's vascular system with proximal loop formation 30 being used for ablation purposes and being arranged, in use, at an ostium of the relevant pulmonary vein.

[0028] However, there are applications where it is desired to place the distal loop formation 26 against a wall of a patient's organ, for example, for heating tumours. In that application, it is desirable that the distal loop formation 26 lies in a plane with no protuberances arranged distally of that plane. This is also advantageous when it is desired to steer the catheter assembly 10 through a patient's vascular system. It will be appreciated that any protuberances distally of the distal end of the sleeve 12 could snag on a wall of the patient's vein or artery as the catheter assembly 10 as being steered resulting in difficulty in steering the assembly and possible damage to the patient's vascular system.

[0029] To form the loop formations 26 and 30 in the tubular member 20 and 22, respectively, each tubular member 20, 22 has an elongate shape-imparting element 32, 34 respectively, extending through the lumen of the tubular members 20, 22.

[0030] Each shape-imparting element 32, 34 is in the form of a length of shape memory alloy wire such as a Nitinol wire.

[0031] The wire 32 protrudes beyond a distal end 36 of the tubular member 20. A distal end 38 of the wire 32 extends back towards a proximal end of the catheter assembly 10 and is anchored on the sleeve 12 proximally of a distal end 40 of the sleeve 12.

[0032] The wire 34 protrudes beyond a distal end 42 of the tubular member 22. A distal end 44 of the wire 34 is anchored to the sleeve 12 approximately in register with the distal end 38 of the wire 32.

[0033] With this arrangement, the loop formation 26 formed at the distal end of the catheter assembly 10 when the tubular member 20 is extended from the sleeve 12 lies substantially in a plane extending transversely to a longitudinal axis of the catheter assembly 10.

[0034] The wire 32 is pre-formed so that, when the tubular member 20 is extended beyond the distal end 40 of the sleeve 12, the loop formation 26 is formed. The loop formation 26 is supported on a cranked arm portion 46. The cranked arm portion 46 projects from the distal end 40 of the tubular member 20 with an included angle 'A' (Figure 3) exceeding 90°. This facilitates the formation of a substantially planar loop formation 26. Similarly, when the tubular member 22 is extended from sleeve 14, the wire 34 imparts the loop formation 30 to the distal portion of the tubular member 22. Once again, the loop formation 30 is supported on a cranked arm portion 48. As is the case with the cranked arm portion 46 of the loop formation 26, the cranked arm portion 48 projects from the sleeve 14 with an included angle 'B' (Figure 1) exceeding 90°. Once again, this facilitates the formation of a substantially planar loop formation 30.

[0035] Each loop formation 26, 30 is in the form of a spiral circumscribing at least 360° and, preferably, about 540°. This ensures that, when a loop formation 26, 30 of maximum diameter is formed, electrodes are arranged substantially all the way around the relevant loop formation 26, 30.

[0036] The portion of wire 32 projecting beyond the distal end 36 of the tubular member 20 forms a bend 50 which is not covered by the tubular member 20. The bend 50 facilitates retraction of the tubular member 20 into the sleeve 12 and wire 32 lies substantially flush with an external surface of the sleeve 12. Hence a compact, small diameter arrangement is formed by the first sleeve 12 and its associated tubular member 20. Similarly, the wire 34 projecting beyond the distal end 42 of the tubular member 22 is cranked relative to the tubular

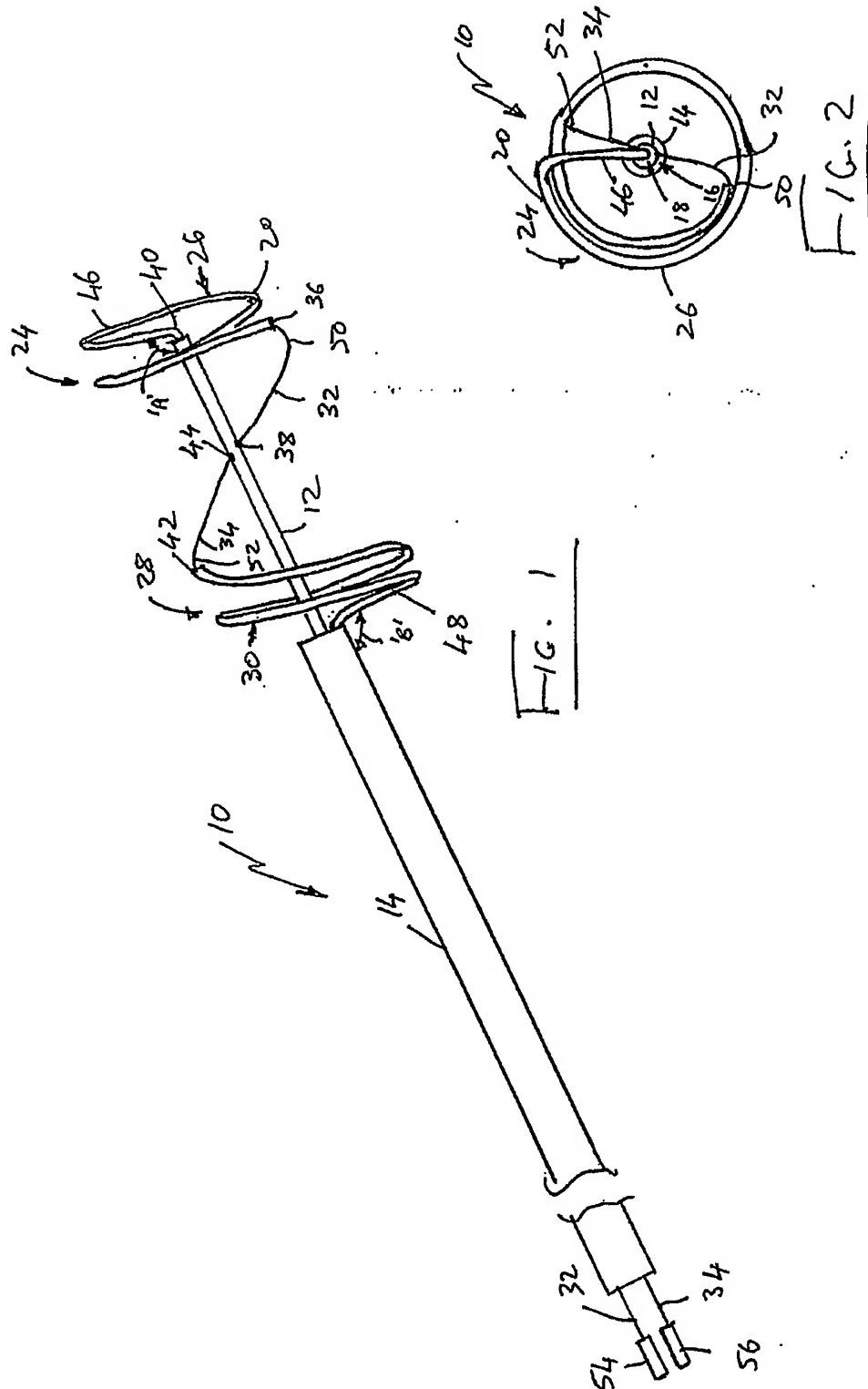
member 22 to form a bend 52. Once again, this facilitates retraction of the tubular member 22 into the sleeve 14 and facilitates the wire 34 lying flush against the outer surface of the tubular member 12. As with the case of the tubular member 20 and its sleeve 12, a compact, smaller diameter arrangement of sleeve 14 and tubular member 22 is provided.

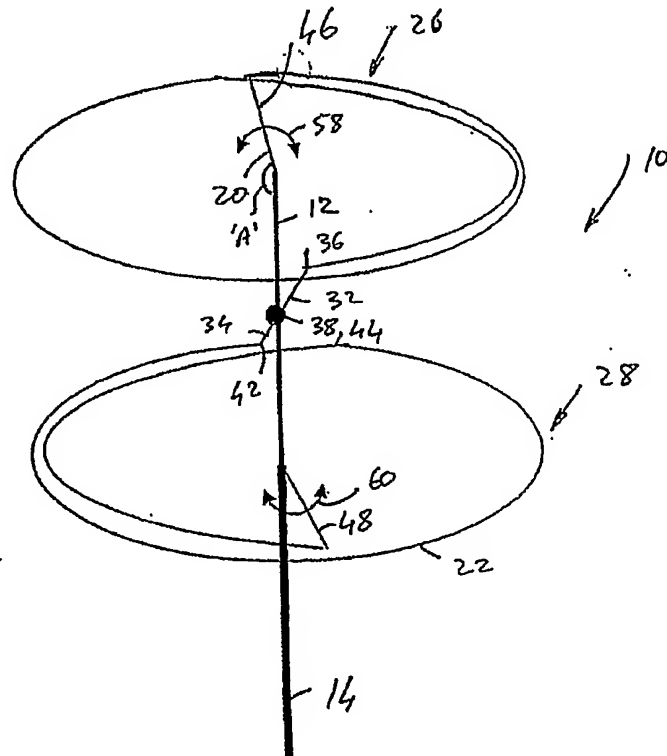
[0037] A proximal end of the wire 32 terminates in an actuating mechanism or actuator 54. Similarly, a proximal end of the wire 34 terminates in an actuating mechanism or actuator 56. The actuators 54, 56 are connected to a loop control mechanism (not shown) of a handle (also not shown) of the catheter assembly 10. For example, the control mechanism may be a thumb wheel for each wire 32 or it may be an electrically activated device.

[0038] By means of the control mechanism, torsion is imparted to each of the wires 32, 34. When torsion is imparted to the wire 32, the cranked arm portion 46 of the tubular member 20 is caused to rotate about the longitudinal axis of the catheter assembly 10 as indicated schematically by arrows 58 in Figure 3 of the drawings. In so doing, the diameter of the loop formation 26 can be increased or decreased as desired. Similarly, by imparting torsion to the wire 34, the cranked arm portion 48 of the tubular member 22 is caused to rotate about the longitudinal axis of the catheter assembly 10 as indicated schematically by the arrows 60. Once again, this facilitates increasing or decreasing the diameter of the loop formation 30 as desired.

[0039] It is, accordingly, an advantage of the invention that a catheter assembly 10 with adjustable loop formations or loops 26, 30 is formed. The absence of any support members for supporting the loops or driving the loops torsionally results in a more compact, smaller diameter catheter assembly 10. This greatly facilitates steering of the catheter assembly through the vascular system of a patient's body. In addition, the fact that no protuberances are required distally of the distal loop formation 26 of the catheter assembly 10 means that the loop formation 26 can be placed in contact with a wall of a patient's vessel or organ to facilitate heat treatment of the vessel or organ, for example, in the treating of tumours. In addition, the absence of any protuberances distally of the distal end of the tubular member 20 of the catheter assembly 10 facilitates steering of the catheter assembly 10 through the vascular system of a patient's body.

[0040] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.



FIG. 3